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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,890	12/02/2003	Steven E. Walak	1001.1632101	3380

28075 7590 01/26/2010

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EXAMINER	
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ART UNIT	PAPER NUMBER
3767	
MAIL DATE	DELIVERY MODE
01/26/2010	PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEVEN E. WALAK

Appeal 2009-009883
Application 10/725,890
Technology Center 3700

Decided: January 25, 2010

Before LINDA M. GAUDETTE, KAREN M. HASTINGS, and MICHAEL P. COLAIANNI, *Administrative Patent Judges*.

COLAIANNI, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellant appeals under 35 U.S.C. § 134 the final rejection of claims 1-22, 25-27, 57-70, and 73.[1] We have jurisdiction over the appeal pursuant to 35 U.S.C. § 6(b).

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[1] The Appeal Brief includes claim 56 as being on appeal. However, the Final Office Action and the Status of Claims section of the Appeal Brief indicate that claim 56 is withdrawn. Therefore, we shall not consider claim 56 on appeal.

We AFFIRM.

Appellant discloses a composite medical device that includes a more flexible inner portion and a less flexible outer portion (Spec. 1).

Claim 1 is illustrative:

1. A composite medical device produced by a process comprising:

constructing a composite elongate shaft by forming a metallic outer portion comprising a first metallic material about a metallic inner portion including a lumen therein, the metallic inner portion comprising a second metallic material different from the first material, wherein the second metallic material is more flexible than the first metallic material, and wherein the composite elongate shaft has a distal region and a proximal region; and

removing a segment of the metallic outer portion from the composite shaft to expose a segment of the metallic inner portion.

The Examiner relies on the following prior art references as evidence of unpatentability:

Viera	US 6,039,699	Mar. 21, 2000
Ren	US 6,045,547	Apr. 4, 2000
Rooney	US 6,306,105 B1	Oct. 23, 2001
O'Brien	WO 99/58184	Nov. 18, 1999

Appellant appeals the following rejection:

1. Claims 1-11, 13, 15, 16, 18-22, 25-27, 57-59, 61, 63, 64, 66-70, and 73 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Ren in view of Viera.[2]

[2] The Examiner's omission of claims 10, 22, 27, and 70 from the statement of rejection (Ans. 3) is harmless error because it is clear from the body of the rejection that claims 10, 22, 27, and 70 are rejected (Ans. 5, 6, and 8). Also,

2. Claims 12, 17, 60, and 65 are rejected under 35 U.S.C. § 103 as being unpatentable over Ren in view of Viera and O'Brien.
3. Claims 14 and 62 are rejected under 35 U.S.C. § 103 as being unpatentable over Ren in view of Viera and Rooney.[3]

With regard to rejection (1) Appellant traverses the rejection of claims 1, 57, and 73 with regard to the same feature. Accordingly, we select claim 1 as representative with claims 2-11, 13, 15, 16, 18-22, 25-27, 57-59, 61, 63, 64, 66-70, and 73 standing or falling therewith. Rejections (2) and (3) are traversed for the same reasons as rejection (1). Accordingly, claims 12, 14, 17, 60, 62, and 65 stand or fall with our analysis of claim 1.

ISSUE

Has Appellant shown that the Examiner reversibly erred in construing the "constructing a composite elongate shaft by forming a metallic outer portion comprising a first metallic material about a metallic inner portion including a lumen" feature of product-by-process claim 1 as including a structure having the composite elongate shaft formed of pre-formed inner and outer metallic portions that are subsequently bonded together by

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the Examiner's omission of claims 58 and 69 from the statement of the rejection (Ans. 3) is harmless error because these claims contain similar subject matter as claims 6, 7, and 27, which were rejected under § 103 over Ren in view of Viera. Appellant does not separately argue claims 6, 7, and 27. Accordingly, it is clear that non-separately argued claims 58 and 69 are likewise rejected under § 103 over Ren in view of Viera. Appellant does not dispute that claims 58 and 69 are under rejection (Br. and Reply Br. *generally*).

[3] Appellant incorrectly states that claim 52 is rejected over Ren in view of Viera and Rooney (Br. 3). The Examiner corrects this mistake and indicates that claim 62 is rejected over Ren in view of Viera and Rooney, which Appellant accepts (Ans. 2; Reply Br. 2).

welding or brazing, for example, such that the claimed invention would have been obvious over Ren in view of Viera? We decide this issue in the negative.

PRINCIPLES OF LAW

The applicant bears the procedural burden of showing error in the Examiner's rejections. *See, e.g., In re Kahn*, 441 F.3d 977, 985-86 (Fed. Cir. 2006) ("On appeal to the Board, an applicant can overcome a rejection [under § 103] by showing insufficient evidence of *prima facie* obviousness") (citation and internal quote omitted).

Product-by-process claims are not specifically discussed in the patent statute. *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985). The practice and governing law have developed in response to the need to enable an applicant to claim an otherwise patentable product that resists definition by other than the process by which it is made. *Id.* For this reason, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. *Id.* Once the Patent Office establishes a prima facie case that the claimed and prior art products appear to be the same or substantially the same, the burden shifts to applicant to show that the products do not possess the same properties (i.e., the products are different). *Id.* at 698.

Claims are given the broadest reasonable construction consistent with the Specification. *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997). The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the

specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364 (Fed. Cir. 2004).

FACTUAL FINDINGS (FF)

We adopt the Examiner's findings on page 4 of the Answer as our own. We add the following primarily for completeness.

1. Appellant does not dispute the Examiner's construction of claim 1 as a product-by-process claim (Ans. 4-5; Br. 11-14).
2. The Specification discloses:

> The elongate shaft 110 can be formed in several different ways. For example, the inner portion 112 and the outer sleeve 114 can be co-drawn, co-extruded, or otherwise processed, for example, over a mandrel or other such structure or device to form the elongate shaft 110 in which the outer portion 114 is of unitary construction with the inner portion 112. In some embodiments, such unitary construction allow the formation of a composite shaft 110 that can be co-drawn and straightened such that the inner portion 112 and the outer portion 114 are formed together as one unitary construction. In other embodiments, the inner portion 112 and the outer portion 114 may be separately manufactured, and thereafter, the outer portion 114 can be disposed about and securely connected to inner portion 112. Some examples of suitable attachment techniques can include, soldering, welding, adhesive bonding, heat bonding, or shrinking techniques, mechanical bonding or fitting, heat crimping, or the like, or combinations thereof.

(Spec. 8-9). In other words, forming the elongate shaft includes forming a unitary construction by either coextruding the inner and

outer portions or separately forming the inner and outer portions and subsequently joining them by welding, for example.

3. Ren discloses a catheter made of layers of polymeric material, the thickness of the layers vary to provide control of the flexibility of the catheter (col. 2, ll. 7-16; col. 3, ll. 11-31; col. 4, ll. 40-59).
4. Ren discloses that the catheter may be formed by an extrusion process (col. 4, ll. 60-62).

ANALYSIS

Appellant argues that a claim feature is missing from the combined teachings of Ren and Viera (Br. 11). Specifically, Appellant contends that the product-by-process feature, "forming an elongate shaft," of claim 1 produces an elongate shaft having an unitary construction, which requires a coextrusion process that bonds the inner and outer portions together along their entire length of the elongated shaft and excludes separately forming and attaching the inner and outer portions via adhesive, welding, brazing or soldering (Br. 11-12).

The Examiner correctly construes the "forming" feature as including a product made by separately forming the inner and outer portions and subsequently bonding them together to form a unitary structure (Ans. 12). The Specification indicates that the elongate shaft may be formed by coextrusion of the inner and outer portions, or separately forming the inner and outer portions and bonding them together to form the shaft (FF 2). Therefore, the structure of the composite medical device implied by the broadest reasonable interpretation of product-by-process feature "forming an elongated shaft" includes separately forming the parts and subsequently

bonding the parts together to form a unitary structure (i.e., separate parts bonded together to form a unified single shaft).

Appellant further contends that separately forming and subsequently bonding the layers together does not form a unitary structure as claimed. However, the claim does not require that a unitary structure is formed by coextrusion. Rather, the claim merely recites "forming an elongated shaft," which, as indicated above, the Specification teaches may include separately forming the individual parts with subsequent bonding of the parts. Accordingly, Appellant's argument that the claims are limited to an elongated shaft having a unitary structure formed by coextrusion is without persuasive merit.

Appellant further argues that one of ordinary skill would look to Ren's coextrusion method of making the catheters that only refers to forming polymer to form a metallic composite medical device as claimed only in view of Appellant's disclosure (i.e., impermissible hindsight) (Br. 12).

However, the Examiner's stated case of obviousness does not necessarily rely on using Ren's coextrusion method to form the metallic materials. Rather, the Examiner finds that Ren and Viera both disclose devices (i.e., guidewires or catheters) that perform nearly the same function (i.e., the ability to guide through the ducts, cavities, and vessels of a person's body), with the exception that guidewires do not have lumens (Ans. 4). Based on these findings the Examiner concludes that it would have been obvious to one of ordinary skill in the art to make the catheter of Ren using the metal materials of Viera (Ans. 4).

The Examiner further explains that the product as claimed could be made by creating the first metallic layer as a loose tube that is then fit over the second metallic layer and then using the bonding methods of Ren or Viera to form the elongated shaft of the composite medical device (Ans. 12). In other words, the Examiner takes the position that the teachings of Ren and Viera as a whole would have suggested forming the claimed metallic elongated shaft having a lumen using the metal forming techniques of Viera.

Appellant's impermissible hindsight argument does not show reversible error in the Examiner's stated case and findings related thereto. Instead, Appellant narrowly focuses the arguments on using Ren's coextrusion method to make a metallic composite medical device as taught by Viera. Accordingly, we are unpersuaded by Appellant's argument.

For the above reasons, we affirm the Examiner's § 103 rejections of claims 1-11, 13, 15, 16, 18-22, 25-27, 57-59, 61, 63, 64, 66-70, and 73 over Ren in view of Viera; claims 12, 17, 60, and 65 over Ren in view of Viera and O'Brien; and claims 14 and 62 over Ren in view of Viera and Rooney.

DECISION

The Examiner's decision is affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

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